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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/417,522	10/13/1999	MICHAEL NEHLS	8535-027-999	7547

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

3/11

Office Action Summary	Application No. 09/417,522	Applicant(s) NEHLS ET AL.	
	Examiner Marjorie A. Moran	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 5-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 5-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. In view of the amendment filed 12/16/03, the rejection of claim 11 under 35 USC 102 is hereby withdrawn. In view of the arguments filed 12/16/03, the new matter rejection of claim 11 is withdrawn.

35 U.S.C. 101/112 Utility Rejections

Claims 3 and 5-13 are again rejected, as previously set forth in the office actions of 7/17/01 and 6/16/03, under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

Applicant's arguments and the exhibit (Exhibit A) filed 12/16/03 have been fully considered but they are not persuasive.

In response to the argument that a gene trap method (i.e. the method of isolation of the instant sequences) enriches for a class of genes, it is noted that a method of purification or isolation does not impute utility to the product isolated. In response to the argument that the "class" of genes are not required for teratocarcinoma cell viability and "are likely" to be involved in cell differentiation and development, it is again noted that there is no evidence for any particular cellular function for any of the claimed SEQ ID NO's, and that a disclosure for what utility or function a sequence is likely NOT to be is not the same as a disclosure for what function a sequence does have.

Applicant argues that the claimed SEQ ID NO's are "functionally validated exons" and presents new evidence that at least portions of the claimed sequences hybridize to exons of particular chromosomes. It is noted that the originally filed specification does

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not teach anywhere that the claimed sequences are “functionally validated exons”, but merely discloses, for example on page 5, that the inventive sequences correspond to endogenous exons. The evidence presented in Exhibit supports that the claimed sequences can hybridize, at least in part, to exons, therefore the sequences do appear to correspond to exons. Whether this correspondence is sufficient to identify the claimed sequences as “functionally validated” is unknown, as neither the specification nor applicant’s arguments provide a definition of the term nor any way to determine if sequences are “functionally validated exons”. Applicant also argues, in light of the new evidence, that as the claimed sequences can be used to “map” to specific locations of specific exons, that a use for gene mapping is a specific utility. In response, applicant is reminded that a utility must have been known and disclosed at the time of invention; i.e. at least as of the time of filing of the instant application. The originally filed specification does disclose, on page 40, that sequences of the instant invention may be mapped to chromosomes and specific regions of chromosomes . The original specification did not disclose, anywhere, which of the many disclosed sequences would be expected to map to which chromosome or particular region. In fact, the instant specification did not disclose any information with regard to individual chromosomes at all, therefore one of ordinary skill in the art would not have been able to determine, at the time of filing, whether ANY disclosed sequence, specifically those claimed, could in fact, have been used in chromosome mapping. The office action of 6/6/03 stated that “it is noted that the specification does not disclose anywhere that any of SEQ ID NO’s 9-18 are known to localize to a particular gene or chromosome, are known to be differentially expressed

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in particular tissues, or are known to be developmentally expressed and/or to regulate any stage of development.” For this reason, one of skill in the art would not have been apprised, at the time of invention, of the “specific” utility now argued by applicants.

In addition, any nucleotide sequence derived from a cell would reasonably be expected to hybridize to the gene or portion thereof from which it is derived. Any cDNA or mRNA would reasonably be expected to hybridize to the complementary exons of the gene from which it is derived, and can be used to “validate” those exons or to determine an exon/intron boundary. Therefore, the mere fact that the claimed sequences hybridize to exons on a chromosome is a “utility” which is generic to the broad classes of at least mRNAs and cDNAs, and is not a specific utility. The instant specification does not disclose a specific, substantial and credible utility for the gene or chromosomal areas to which the claimed sequences bind. Further, applicant is reminded that a utility is one which offers an “immediate benefit” to the public. Of what “immediate benefit” is the knowledge that a sequence binds to a particular chromosomal section, wherein nothing is known of that section?

For the reason previously set forth and set forth above, the rejection is maintained.

Claims 3 and 5-13 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

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the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments filed 12/16/03 have been fully considered but they are not persuasive. Applicant argues that as the claimed sequences have utility, one would know how to use them. As set forth above, the examiner the rejection with regard to utility is maintained, therefore the rejection for lack of enablement is also maintained.

Claim Rejections - 35 USC ' 112

Claims 3 and 10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

Applicant's arguments filed 12/16/03 have been fully considered but they are not persuasive. Applicant admits that numerous polynucleotides fall within the scope of the claims, and that claim 13 describes a genus of sequences by a property, but argues that the sequences encompassed by the claims are nonetheless described by the disclosure of the exact structures of the claimed SEQ ID NO's. In response, it is again noted that the claims encompass a wide variety of possible sequences, not described by the instant specification, such that one skilled in the art could not envision the members of the genus. In response to the argument that one skilled in the art can readily compare sequences to determine if one hybridizes, it is noted that the rejection is not one of enablement (i.e. can one determine...), but is one of description. As previously set forth, the fact that one skilled in the art can identify and distinguish polypeptides based on

hybridization properties does not constitute a written description of the polypeptide, sequence, structure, etc. so identified.

For these reasons and those previously set forth, the examiner maintains that none of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claims, therefore the rejection is maintained.

Claims 10 and 13 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Isolated polynucleotides comprising a contiguous stretch of "at least about 30 nucleotides" and "at least about 40 nucleotides capable of hybridizing...." are new matter. Applicant points to page 16 of the specification for support for "at least about 40", therefore the rejection of claim 11 is hereby withdrawn. Page 16 discloses "about 30" nucleotides, but does not teach a contiguous stretch of "at least about 30" nor any length which is "capable of hybridizing". None of the original claims recited a sequence comprising a contiguous stretch of "at least about 30" or "at least about 40 nucleotides capable of hybridizing" to another. Claims 10 and 13 are not original claims. As neither the originally filed specification or claims provide support for the limitations of claims 10 and 13, the rejection is maintained.

Conclusion

No claims are allowed

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

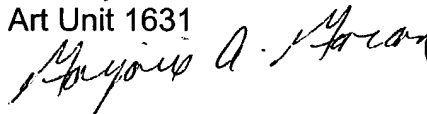
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631



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